Complete Summary

GUIDELINE TITLE

Bronchitis.

BIBLIOGRAPHIC SOURCE(S)

Bronchitis. Philadelphia (PA): Intracorp; 2005. Various p. [20 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from April 1, 2005 to April 1, 2007.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the <u>FDA Web site</u> for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide

to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the <u>FDA Web</u> site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Acute bronchitis
 - Viral bronchitis
 - Bacterial bronchitis
 - Bronchitis attributed to histamine response
- Chronic bronchitis

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Family Practice Infectious Diseases Internal Medicine Pulmonary Medicine

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUI DELI NE OBJECTI VE(S)

To present recommendations for the diagnosis, treatment, and management of bronchitis that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with bronchitis

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

- 1. Physical examination and assessment of signs and symptoms
- 2. Diagnostic tests:
 - C-reactive protein (CRP) test
 - Complete blood count
 - Pulse oximetry
 - Arterial blood gasses
 - Pulmonary function tests
 - Serum procalcitonin assays (under investigation)

Note: Guideline developers considered but did not recommend sputum gram stain to determine the cause of bronchitis or responsiveness to antimicrobial therapy

Management/Treatment

- 1. Antivirals (amantadine, rimantadine, ribavirin)
- 2. Antibacterials for bacterial bronchitis only
- 3. Bronchodilators (albuterol)
- 4. Analgesic or antipyretic agents
- 5. Antitussive treatment (codeine, dextromethorphan)
- 6. Vaporizer
- 7. Elimination of environmental triggers
- 8. Patient education regarding effective cough, deep breathing exercises, postural drainage, and smoking cessation
- 9. Referral to specialists

MAJOR OUTCOMES CONSIDERED

- Sensitivity, specificity, and utility of diagnostic tests
- Effectiveness of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE FVI DENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of

a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Persistent cough
 - May be worse at night (recumbent position)
 - Usually productive of sputum
- Dyspnea on exertion
- Fatigue
- Sore throat (pharyngitis)
- Hoarseness (laryngitis)
- Substernal chest discomfort
- Malaise
- Headache

Objective Findings

- Low-grade fever
- Persistent cough, with or without:

- Rhinorrhea (suggests rhinovirus)
- Fever (suggests influenza and adenovirus or bacterial infection)
- Sputum production (may or may not be purulent)
- Audible wheezing
- Rales or rhonchi with influenza infection, adenovirus, chlamydia, or mycoplasma
- Wheezing secondary to bronchospasm
- Skin rash (25% of cases of mycoplasma)
- Laryngitis (more common with chlamydia)

Diagnostic Tests

- C-reactive protein (CRP): rapid CRP test has recently been U.S. Food and Drug Administration (FDA) approved, and studies show a high sensitivity (80 to 100%) but low specificity (60 to 70%) to identify bacterial infection
- Complete blood count: white blood cell (WBCs) count elevated in about 25% of cases
- Pulse oximetry, arterial blood gases, pulmonary function tests
 - Evaluate O₂ saturation on room air
- Sputum gram stain is NOT effective in determining the cause of bronchitis or responsiveness to antimicrobial therapy.
- Serum procalcitonin assays are also being studied in conjunction with lower respiratory tract infection (LRTI) clinical algorithms, to definitely direct antibiotic usage: to date these findings are inconclusive.

Differential Diagnosis

- Asthma (see the Intracorp guideline Asthma)
- Acute exacerbation of chronic bronchitis (especially in a middle-aged smoker)
- Sinusitis
- Pneumonia (see the Intracorp guideline Pneumonia, Community-Acquired)
- Congestive heart failure (CHF) (see the Intracorp guideline Congestive Heart Failure)
- Pulmonary embolism (PE) (see the Intracorp guideline Pulmonary Embolism)
- Vasculitis
- Pulmonary malignancy (see the Intracorp guideline Lung Cancer)
- Environmental exposure
- Allergic pneumonitis
- Underlying chronic bronchitis or pulmonary disease

Treatment

Treatment Options

- Neuraminidase inhibitor therapy
 - Antivirals
 - Amantadine or rimantadine therapy for influenza A may lead to a significant shortening in duration of illness when given within 48 hours of onset.
 - Rarely aerosolized ribavirin may be of modest benefit in adults with bronchitis due to respiratory syncytial virus (RSV).
 - Antibacterials

- Antibiotics have little or no benefit in treating acute bronchitis and should not be used unless convincing evidence of bacterial infection is present.
- Bronchodilation
 - Albuterol
- Analgesic or antipyretic agents
 - Acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs)
- Antitussive treatment
 - Codeine or dextromethorphan for cough suppression
- Vaporizer
- Elimination of environmental triggers
- Patient education
 - Pulmonary toilet: effective cough, deep breathing exercises, postural drainage
 - Smoking cessation

Duration of Medical Treatment

- Medical Acute Bronchitis Optimal: 5 day(s), Maximal: 14 day(s)
- Chronic or Asthmatic Bronchitis Optimal 14 days, Maximal Lifetime

Additional information regarding primary care visit schedules, referral options, specialty care, and durable medical equipment is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Resolving cough, dyspnea, bronchospasm
- After resolution of infection
- After hospitalization

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, and management of bronchitis to assist medical management leaders to make appropriate benefit coverage determinations

Specific Potential Benefits

- Studies of C-reactive protein (CRP) show a high sensitivity (80-100%) but low specificity (60-70%) to identify bacterial infection.
- Amantadine or rimantadine therapy for influenza A may lead to a significant shortening in duration of illness when given within 48 hours of onset.
- Rarely aerosolized ribavirin may be of modest benefit in adults with bronchitis due to respiratory syncytial virus (RSV).

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2005)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 31, 2005. The information was verified by the guideline developer on June 7, 2005.

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